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WELCOME

Advancing Care, One Breath at a Time

Seabreeze STAT Trials Investigator Meeting

San Diego, CA | Friday, September 12, 2025

Investigator Meeting Agenda | San Diego, CA

Seabreeze STAT Trials - ***Advancing Care, One Breath at a Time***

Time (PT)	Session Title	Speaker(s)
08:30–08:40	**Welcome to Seabreeze STAT Trials:** Why This Program Matters	Dr. Barry Quart (Connect)
08:40–08:55	**Meet the Minds Behind the Mission (Introductions & Team Overview)** 🎉 *Trivia Showdown - Compete for prizes while mastering the protocols*	Dr. Raul Collazo, Master of Ceremonies (Connect)
08:55–09:10	**Tech Check:** iPad Setup & Interactive Tools Demo	Turner Papke (Array)
09:10–09:45	🎉 **Rademikibart Revealed:** The Science Driving the Trials + Live Q&A	Dr. Cristian Rodriguez (Connect)
09:45–10:00	🎉 **Safety Snapshot & Reporting**	Kimberly Manhard (Connect)
10:00–10:20	-- *Break & Take a Breather*	—
10:20–11:20	🎉 **Protocol Power Hour:** Asthma & COPD Essentials + Live Q&A	Dr. Marisa “MJ” Jones, Guy Boccia (Connect)
11:20–12:00	**Breath by Breath:** Spirometry & FeNO in Action	Dr. Erin Lennox (ZEPHYRx)
12:00–01:30	-- **Lunch & Learning Stations** • Spirometry Demo • Study Start-Up Station	All
01:30-01:40	**Diving into Labs:** Navigating Blood and the Lab Workflow	Guy Boccia (Connect)
01:40–01:50	🎉 **Behind the Scenes:** How Safety Committees Keep Trials on Course	Radha Adivikolanu (Connect)
01:50–02:50	**Recruitment That Works:** • Top Tips from an Expert • Table Talk / Voicing Innovative Recruitment	 Dr. Sanjay Ramakrishnan (ABRA Lead Investigator) All
02:50–03:10	**Tech at the Core:** Randomization Meets Data	Guy Boccia (Connect)
03:10–03:25	-- *Break & Moment to Breathe*	—
03:25–04:10	🎉 **Study Expectations & Monitoring with Meaning:** Oversight to Drive Quality	Aubree Malan (ProPharma Group)
04:10–04:30	**Closing Notes and Winning Moments (Trivia Champions!)**	All

🎉 **Trivia Tip:** Watch for this symbol on the agenda - fastest correct responders have a shot at *prizes*.

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Break – Return at **03:35 pm PT**

A Moment to Breathe 

- Step into the foyer for light bites and a refreshing pause.

Study Expectations & Monitoring with Meaning

Oversight to Drive Quality

Aubree Malan
Senior Clinical Lead, ProPharma Group

Clinical Monitoring

Definition

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), and Good Clinical Practice (GCP)

Purpose

- To verify that the reported trial data are accurate, complete, and verifiable from the source document
- To verify that the conduct of the trial complies with the current approved protocol/amendments, with GCP, and with the applicable regulatory requirements

Expectations

- Investigator must be available during remote and on-site monitoring visits.
- During the remote or on-site visit, the Investigator/Site Staff should have access to:
  - Source documents
  - IRT/EDC for data review and query resolution
- Investigator Site File (ISF) and essential documents
- During an on-site visit, monitors should have access to all study documents and source data (paper and electronic)
- Regular site management calls will be performed as a quick touch base with sites to inquire about study progress and provide guidance on any issues/concerns.

Monitoring Visits and Frequency
Visit Schedule

On-site Visits

- **1st Monitoring visit** to occur within ~1 week after first 2 participants screened or first participant dosed
- ~every 3-4 weeks

Remote Monitoring Visits

- As needed

Frequency Triggers

- Enrollment
- Urgent issues
- Source data verification (SDV) backlog
- Major study milestones (eg, interim analysis)

Monitoring Visits Communication

Visit Confirmation

- Confirmation letter/email will be sent prior to every remote and on-site visit. It will contain details on documents expected to be reviewed during the visit to ease your preparation

Follow-Up Letter will be sent after every monitoring visit (within 21 business days)

Summarizing:

- Any findings/issues that arose during the site visit
- Any pending action items (should be resolved within 10 days of issue)
- Any requirements for the next site visit

Review all correspondence and file it in the appropriate section of the ISF

Investigator Site File (ISF)

Regular Site Contact

To be discussed:

- Verification of study data and query resolution
- Discuss/review of all pending actions
- Obtain essential documents
- Staff or site changes

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Question

How often are routine monitoring visits performed?:

A: Every 6-8 weeks

B: Every 3-4 weeks

C: Every 4 months

D: As needed, risk based

Investigator Responsibilities

- The Investigator shall be responsible for the day-to-day conduct of the study at the site, including the periodic reporting of study progress and quality assurance.
- Investigators are responsible for detecting and documenting events that meet the definition of an AE, SAE, AESI, suspected DILI, UADE, or pregnancy as specified in the protocol.
- Investigators must review the Investigator's Brochure to be aware of safety-related events that may be anticipated with its use.
  - Investigators should also be well-versed in the latest standard of care guidelines.
- Investigators shall ensure that personal identifiers are removed from study files accessible to non-study personnel, in accordance with applicable laws and regulations.
  - Study files should be coded and stripped of personal identifiers, and code keys stored separately from study files.
  - Delegated study staff responsible for data integrity (computerized or hard copy), shall have the education, training, and experience needed to perform the assigned tasks.

Investigator Responsibilities (continued)

- Before and during the trial, the Investigator should provide all IRB/IEC documents for review and also obtain written approval before the study begins.
- All data collected for the study should be recorded accurately, promptly, and legibly
- All procedures used to obtain, verify, and promote the quality and integrity of the data should be recorded in sufficient detail so that others can replicate them.
  - A historical file of these procedures shall be maintained, including all revisions and the dates of such revisions.
  - Any changes in data entries shall be documented.
- Security of data should be maintained at all times.
  - Access should be limited to authorized individuals.
  - Control systems, such as document encryption, should be used to ensure the authenticity, integrity, and confidentiality of electronic records when transmitted over open networks (e.g., the internet).
- Adequate backup of the data should be maintained throughout the course of the study.

Question

Who is responsible for day-to-day conduct at the site?:

A: The Sponsor, Connect BioPharma

B: The CRO, ProPharma

C: The Primary Study Coordinator

D: The Investigator

Other Investigator Responsibilities

Communication with IRB/IEC

- Should have written, dated approval/ favorable opinion for trial protocol, subject recruitment procedures, and other information to be given to trial subjects.
- Provide all documents subject to review.

Compliance with Protocol

- Conduct the trial in compliance with the protocol
- **Should not deviate, except in case of emergencies.**
- If an Investigator deviates from the protocol, he/she is required to:
  - Document and explain any deviation from the agreed protocol in a written document.

Maintain Records and Provide Reports

- The Investigator is obliged to keep and maintain records and submit required reports
- Upon request of the monitor, auditor, IRB/IEC or the regulatory authority, the investigator should make available direct access to all requested trial-related records
- Data must be complete and ALCOA-CCEA complaint.
- How and where the data is recorded is key! If it is not documented, it does not exist.
- Data entered into the IRT/EDC should match the source documents (raw data).

Question

What is the criteria for protocol waivers?

A. When a participant has borderline lab values
B. When participants are on vacation
C. Never
D. When participant is on a needed exclusionary medication
E. When site staff is unavailable

Noncompliance and Protocol Deviations (PDs)

- A Protocol Deviation is a change, divergence, or departure from the study design or procedures defined in the protocol.

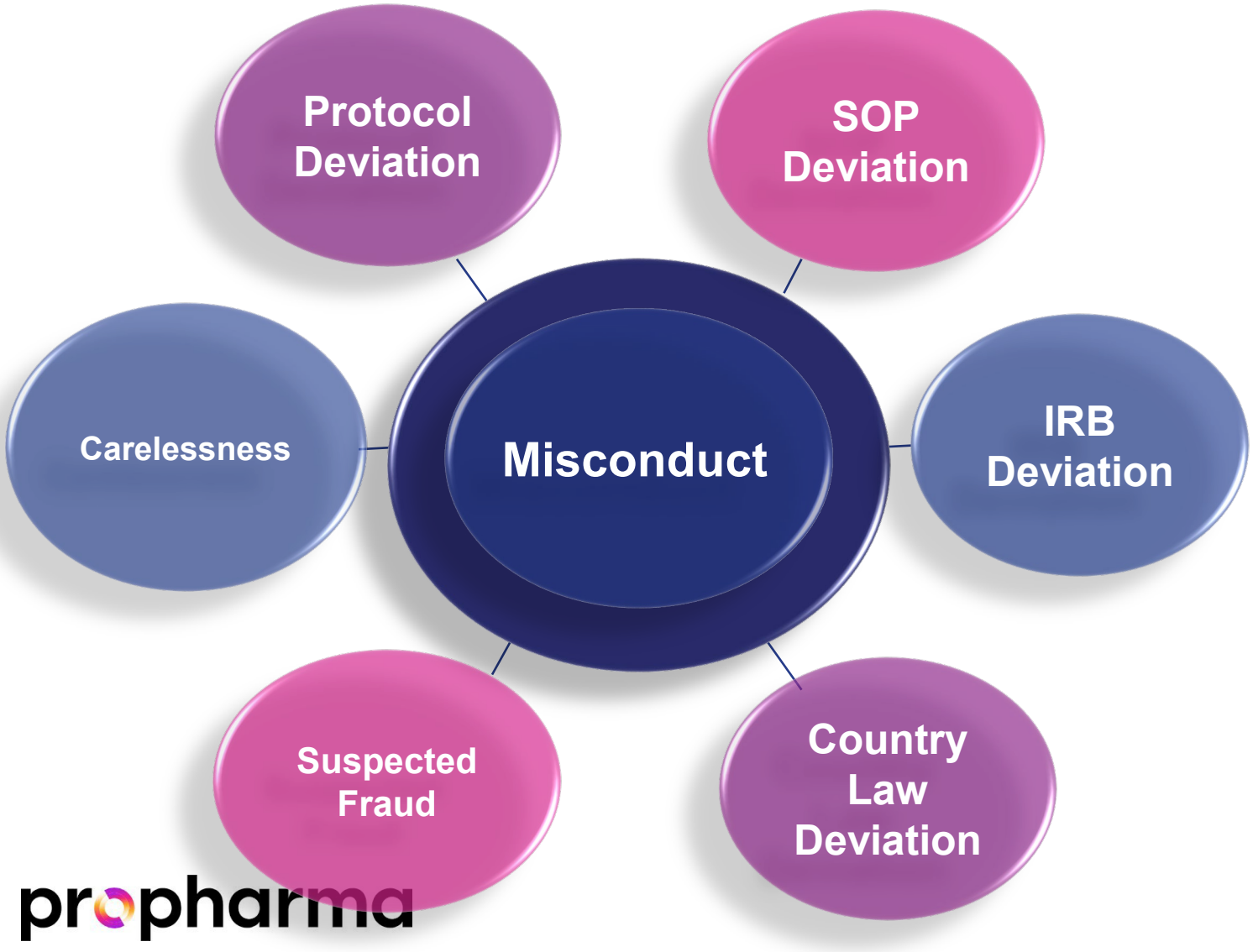
- Noncompliance and Protocol Deviations (PDs)

Common types of deviations:

1. Informed consent not properly obtained
2. Out-of-window participant visits
3. Incorrect dosing
4. Unreported SAEs
5. Enrolling ineligible participants

- Note: Protocol deviation and eligibility waivers ***are not granted*** for this protocol

Noncompliance and Protocol Deviations (PDs)



Noncompliance and PDs can lead to:

- Invalidation of data
- Erroneous results
- Regulatory impact

Deviations should be reported to the IRB/IEC if they meet the central and/or local IRB reporting requirements.

Question

What is an example of an important protocol deviation?

A. Enrolling a patient with an eosinophil count of 200 cells/μL
B. Failure to obtain informed consent
C. Failure to collect data for important trial endpoints
D. Administered wrong investigational product to the patient
E. All of the above

ICH-GCP Guidelines

- ICH-GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human participants

- Key Objectives of ICH-GCP:
  - Protect the rights, safety, and well-being of trial participants
  - Ensure the credibility and accuracy of clinical trial data
  - Provide a unified standard for research

ALCOA CCEA

COMPLETE
Maintain adequate, accurate and complete source documents

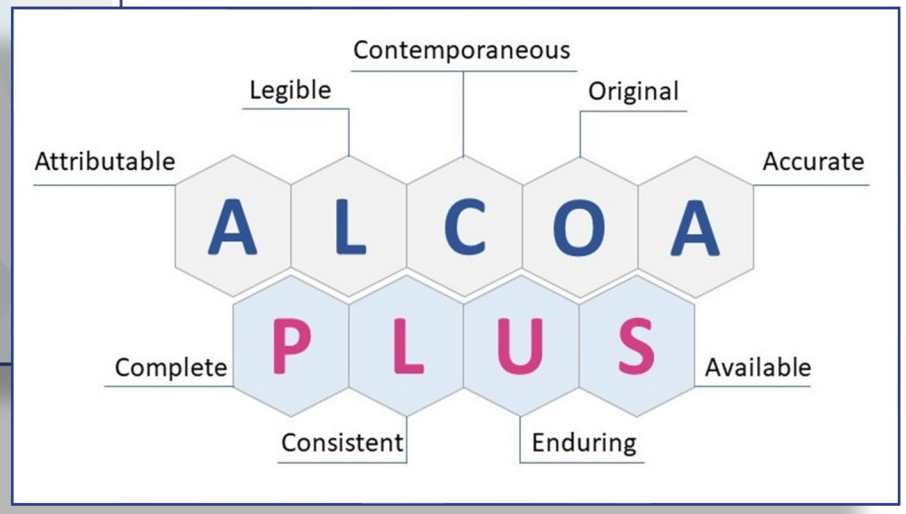
ATTRIBUTABLE
Obvious who created a document and when
Who made a change, when it was made, and why

ACCURATE
High level of honesty and accuracy in reporting
Double checked for accuracy

LEGIBLE
The record should be easily read

ORIGINAL
Study record should be original, not a photocopy

CONTEMPORANEOUS
Results recorded as they are observed
Signautres attached to a date when it occured



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Good Documentation Practices

- If it happened, write it down!
- Write in detail, as this will avoid questions and doubts from monitors, auditors, or inspectors.
- Wherever something was first written or entered becomes a source document.
- Always retain and archive source documents as required by regulations.
- Establish a good filing practice.
- Keep hard copies of all computer information.
- Ensure controlled access.
- Always update the study files!

Why is Source Data verified?

- To confirm the patient's existence.
- To have documentation confirming the diagnosis of the disease/ medical condition.
- To ensure the integrity and quality of the study data for the clinical trial.

If it's not documented, it never happened!

Question

Of the below, which example ***does not*** meet ALCOA+?:

A: Study coordinator measures vitals at 09:00, and records them in source at the end of the day

B: Investigator writes ‘NCS’ on an abnormal lab range, initials/dates next to entry

C: Regulatory coordinator makes all documents available to the monitor during an IMV

D: A study coordinator files the original print out from the ECG machine in the patient’s paper chart.

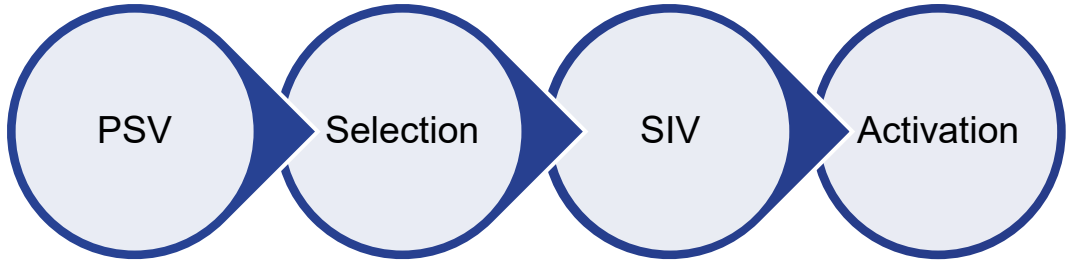
Site Activation – Required Items

Regulatory and Access Confirmation

- Site Delegation of Authority Log
  - Minimum of Investigator and 1 additional staff member
- SIV Training Log
- Source Data Agreement
- Confirmation of EDC (Medrio) access
  - Minimum of Investigator and 1 additional staff member
- Confirmation of IRT (Suvoda) access
  - Minimum of Investigator and 1 additional staff member
- Confirmation of ZEPHYRx access
- Confirmation of Labconnect access
  - Minimum of Investigator and 1 additional staff member

Study Supplies

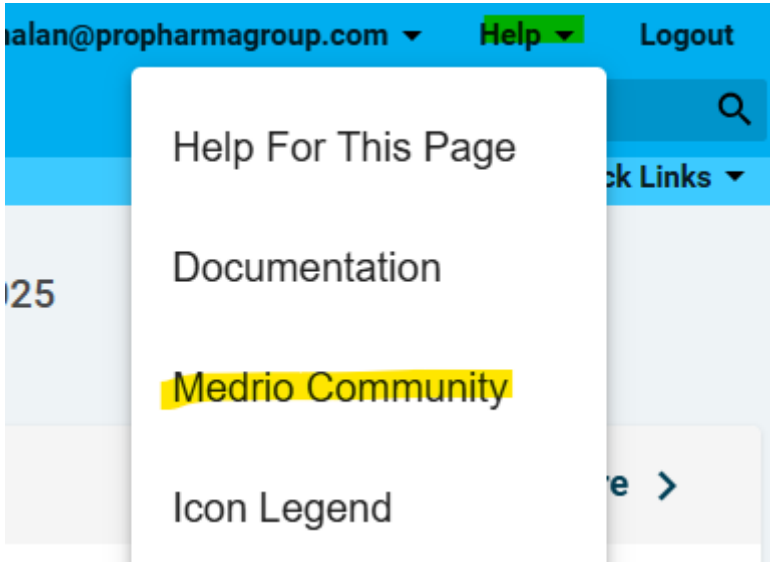
- Labconnect kits onsite
- ZEPHYRx study supplies onsite
- IP kits onsite and fit for use
- Pharmacy Binder and eISF received

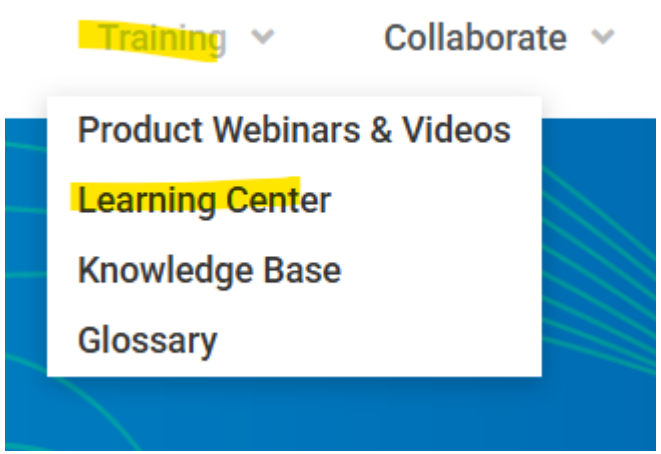


Medrio EDC Access

Once you send your site contact form to your CRA, Medrio access will be requested for all personnel indicated.

Please login to Medrio per the welcome email instructions. ***After logging in, E-Learning is required to gain access to the study.***





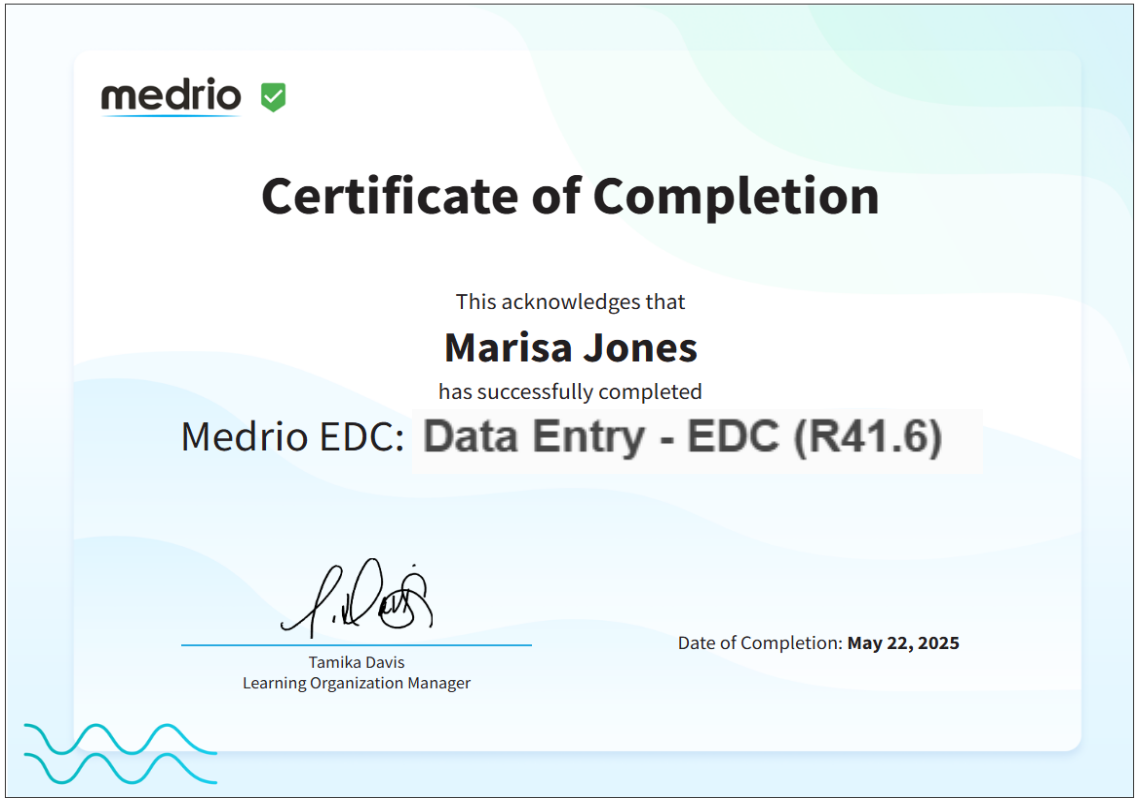
Data Entry - EDC (R41.6)
Data entry for Site Users using Medrio EDC as of version R41.6

Medrio EDC Access

- After you complete eLearning, you will receive a certificate. This certificate must be emailed to the below contacts in order for full study access to be granted.

CBP-201-206 & CBP-201-207:
Munim Saeed
Munim.Saeed@precisionformedicine.com

Please include your CRA for awareness and internal filing purposes

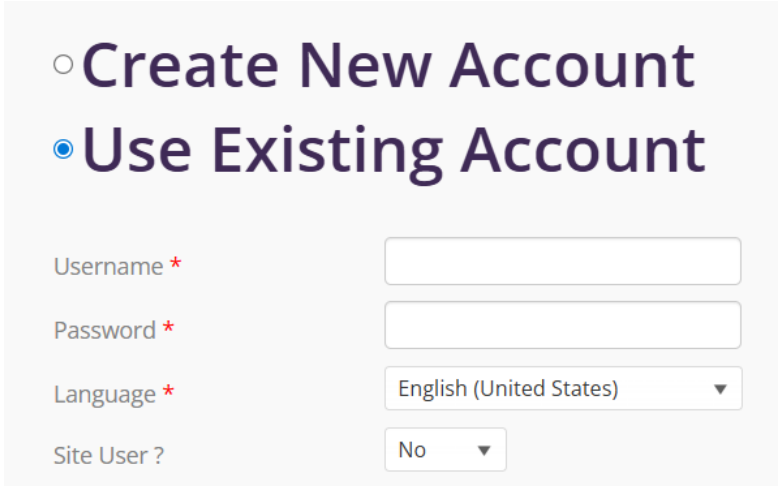


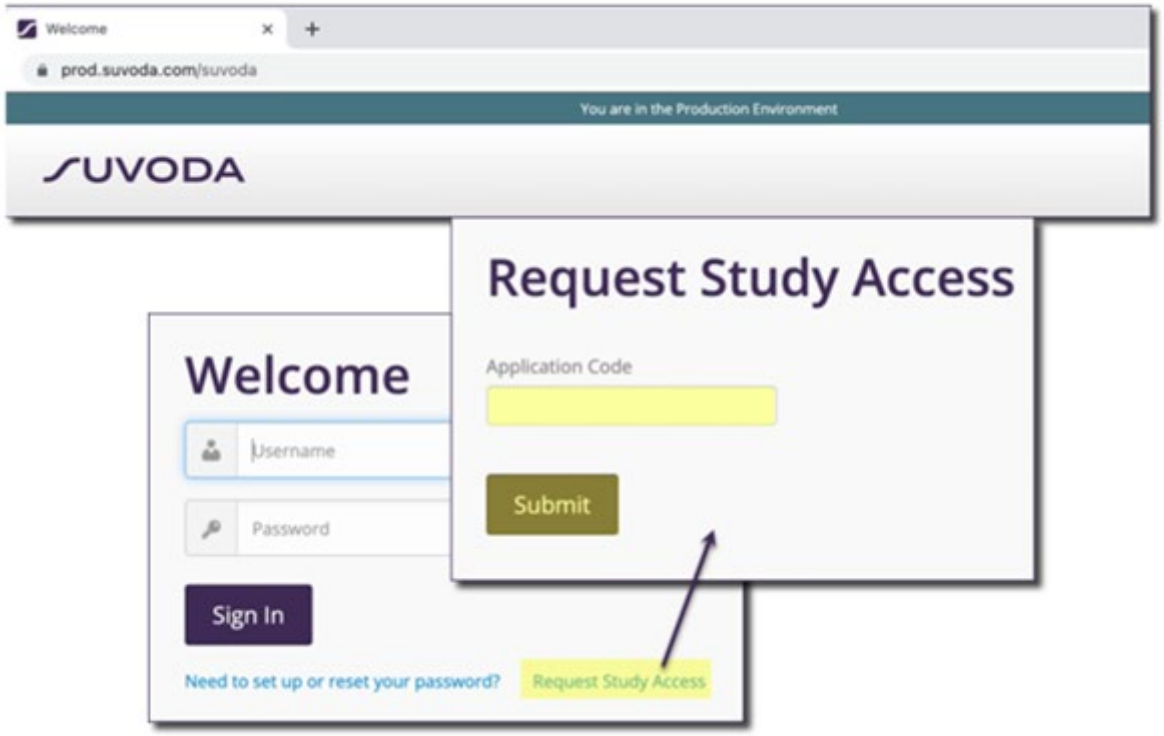
Suvoda IRT Access

Access to Suvoda is Self-Requested

- Navigate to prod.suvoda.com/suvoda
- Click Request Study Access
- Enter Study Code

Study Code: Connect-CBP-201-206
Study Code: Connect-CBP-201-207





Note: To utilize the same user name for both studies, click ‘Use Existing Account’ on your second study access request

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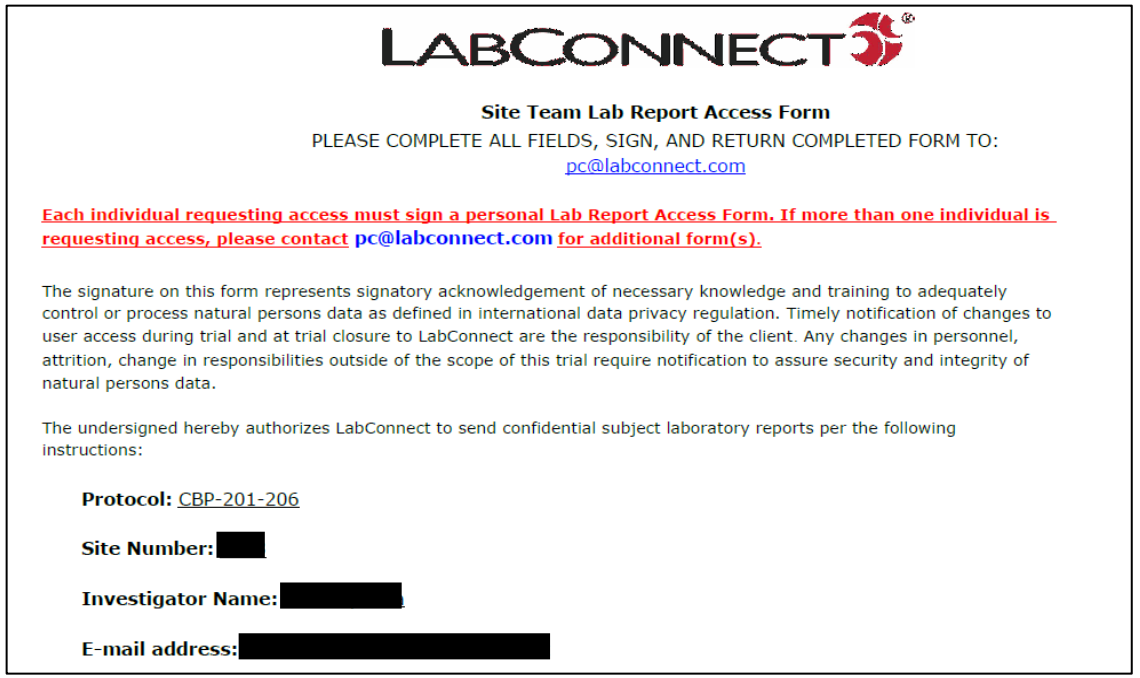
LabConnect Access

Once you send your site contact form to your CRA, Medrio access will be requested for all personnel indicated.

After access request has been processed, you will have to complete a verification form ***for both studies*** in order to gain access to the portal.

Once the access form is complete, it should be emailed to PC@labconnect.com

Note: Several sites have not received LabConnect access emails. Please check spam and search for remote@labconnect.com – as this is who the email will come from



LABCONNECT

Site Team Lab Report Access Form

PLEASE COMPLETE ALL FIELDS, SIGN, AND RETURN COMPLETED FORM TO:
pc@labconnect.com

Each individual requesting access must sign a personal Lab Report Access Form. If more than one individual is requesting access, please contact pc@labconnect.com for additional form(s).

The signature on this form represents signatory acknowledgement of necessary knowledge and training to adequately control or process natural persons data as defined in international data privacy regulation. Timely notification of changes to user access during trial and at trial closure to LabConnect are the responsibility of the client. Any changes in personnel, attrition, change in responsibilities outside of the scope of this trial require notification to assure security and integrity of natural persons data.

The undersigned hereby authorizes LabConnect to send confidential subject laboratory reports per the following instructions:

Protocol: CBP-201-206

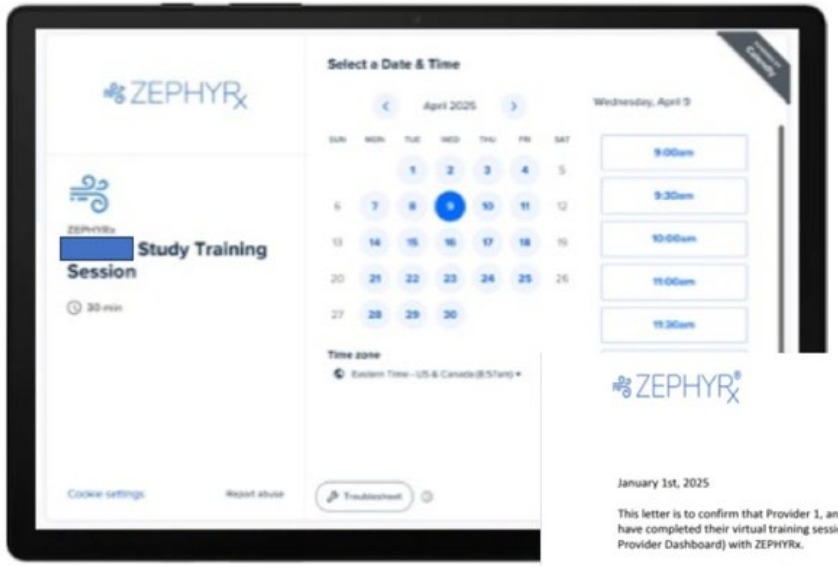
Site Number: [redacted]

Investigator Name: [redacted]

E-mail address: [redacted]

ZEPHYRx Access

- The vendor will reach out with your site directly to schedule training once all equipment has been received at your site. This is a 1-hour virtual training and you will receive a certificate after completion.



January 1st, 2025

This letter is to confirm that Provider 1, and Provider 2 from the [redacted] trial site XXXX have completed their virtual training session for the ZEPHYRx Platform (Spirometry, and Provider Dashboard) with ZEPHYRx.

Completion Date: January 1st, 2025

Erin Lennox
Research and Clinical Trials Manager
ZEPHYRx

Please note:

- There is one training performed per site – it is a group training, so all team members should be present for the live demonstration.
- ***Supplies must be available*** during the training as this is a hands-on training.

For new site staff that require access, submit a support request at www.zephyrx.com/seabreeze

Question

To which vendor site can you self-request access?

A: Medrio EDC

B: Suvoda IRT

C: ZEPHYRx

D: LabConnect

Overall Study Status*

Site Status (Global)

Selected	• Asthma: 56 • COPD: 52
Activated	• Asthma: 5 • COPD: 4
Enrolling	• Asthma: 1 • COPD: 1

Participant Status (Global)

Screened	• Asthma: 5 • COPD: 12
Dosed	• Asthma: 0 • COPD: 0
Screen Failed	• Asthma: 0 • COPD: 3

*Totals as of 10Sep2025

Meeting Close & Winners Announced!

Raul Collazo, PhD
VP, Global Medical Strategy

Questions & Answers